

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1037554	<b>(X3) Date Survey Completed</b> 11/17/2022
<b>Name of Provider or Supplier</b> Raymondville Pediatrics	<b>Street Address, City, State</b> 640 S Expressway 77, Suite 2, Raymondville, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
<b>D2007</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's American Proficiency Institute (API) proficiency testing records from 2021 (events 1, 2, and 3) and 2022 (events 1 and 2), and confirmed in laboratory staff interview, the laboratory failed to ensure 2 of 3 testing personnel performing patient testing in 2021 participated in proficiency testing. The findings included: 1. A review of the laboratory's submitted Form CMS 209 found the laboratory identified 3 testing personnel who performed patient testing from January 1, 2021 to December 31, 2021. 2. A review of the laboratory's API proficiency testing records from 2021 (events 1, 2, and 3) and 2022 (events 1 and 2) found the laboratory failed to have documentation of 2 of 3 testing personnel participating in proficiency testing in 2021. They were (as listed on Form CMS 209) as follows: Testing personnel number 2 Testing personnel number 3 3. The laboratory was asked to provide documentation of the identified personnel participating in proficiency testing in 2021. No documentation was provided. 4. An interview with the technical consultant on November 17, 2022 at 09:30 hours in the patient exam room confirmed the findings. Key: CMS - Centers for Medicare and Medicaid Services</p>

**D5311****SPECIMEN SUBMISSION, HANDLING, AND REFERRAL**

CFR(s): 493.1242(a)

The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.

This STANDARD is not met as evidenced by:

Based on surveyor observation, review of laboratory policies, and confirmed in interview of laboratory personnel, the laboratory failed to follow its own policy for specimen labeling for 10 of 11 samples observed on November 17, 2022 (the date of the onsite inspection). The findings included: 1. Surveyor observation on November 17, 2022 at 09:09 hours in the laboratory found 11 pediatric samples located in a specimen rack on top of the Sysmex analyzer. - 2 samples were labeled with first name - 8 samples were not labeled - 1 sample was labeled according to policy 2. Review of the laboratory's policy titled, "Specimen Identification" approved by the laboratory director on January 31, 2005, stated, "Each specimen must have unique patient identifiers such as patient name, birth date, social security number, or other identifying number. The identification should be used throughout the testing process, so that results can be confidently used in patient care ...)" 3. The findings were confirmed with the technical consultant on November 17, 2022 at 09:12 hours in the laboratory.